



# UNITED STATES PATENT AND TRADEMARK OFFICE

EST

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327
21036	7590	05/31/2006	EXAMINER	
MCLEOD & MOYNE, P.C. 2190 COMMONS PARKWAY OKEMOS, MI 48864			LEITH, PATRICIA A	
			ART UNIT	PAPER NUMBER

1655

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
---------------------------------	-------------	---	---------------------

EXAMINER
----------

ART UNIT	PAPER
----------	-------

042706

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents****COMMUNICATION AFTER REMAND TO THE EXAMINER**

This communication is set forth in order to fulfill the requirement of "entering Dekazos into the record and to consider the issues raised by appellants relying on this reference in the reply brief as we have stated these issues above, in light of our finding and discussion above" as presented by the Board of Appeals in the Remand to the Examiner of March 30, 2006.

The Examiner hereby officially enters Dekazos into the record by submitting a PTO-892 form into the record including Dekazos as a reference.

The Dekazos reference was fully considered by the Examiner on the date specified by the record as per the communication entered into the record on 2/24/04.

The Examiner has fully considered Appellants' arguments:

Appellants argue first that they disagree with the Examiner's statement that "it is further noted that cyanidin is found in nature in the glycosidic anthocyanin form as displayed below" in light of Dekazos, E.d., J. of Food Science 35 237-241 (1970). Appellants contend that Dekazos:

"clearly identified 'cyanidin' as a color pigment in the skin. Since the anthocyanins occur in the pulp as well, it is very likely that they would occur in the pulp. In any event, in Applicants' Examples 1 and 2 the whole cherry (including the skin) was blended in the WARING blender. Thus, cyanidin clearly occurs in nature and is in the naturally derived compositions described in the application. The hydrolyzed glycosylated anthocyanins were used to obtain enough for testing in the Examples" (page 2, Reply Brief).

First, with regard to wherein Appellants state that Dekazos "...clearly identified 'cyanidin' as a color pigment in the skin. Since the anthocyanins occur in the pulp as well, it is very likely that they would occur in the pulp", it is deemed that while it is accepted that cyanidin is a color pigment in cherries, the Examiner retains the opinion that cyanidin is found in nature in the glycosidic form and not in the aglycon, or otherwise known as 'aglycone' form of cyanidin which does not include a glycoside. The reason that the Examiner retains this opinion is that there is no clear evidence on the record or in the prior art that the Examiner is aware of which indicates that cyanidin occurs in nature in the aglycone form.

To expound, Dekazos evaluated the pigments in Montmorency cherries by extracting the skin of frozen Montmorency cherries with

cold methanol containing 0.1% HCl (v/v) followed by chromatographic separation of the pigments (see page 237). It is true that cyanidin is among the pigments displayed in Table 2 as being an isolated compound from the extraction. However, Dekazos further states that:

"The first 2 pigments of this study were found to be cyanidin and peonidin. The existence of the anthocyanin in free unpurified pigment extract has been confirmed in other studies. Since it has been said that anthocyanins are unlikely to occur naturally in plant tissues in the free state, chromatograms of extracts were run with minutes of extracting tissue (skin of overripe, fresh red tart cherries with ice-cold methanol containing 0.1% conc HCL...at 32 ° F to minimize hydrolysis....Special effort was expended to minimize hydrolysis; however, it might possibly still occur" (page 240, emphasis added).

Here, Dekazos indicates that they do not know if the cyanidin and peonidin aglycones were naturally occurring, or were hydrolyzed during processing to isolate the pigments. It is entirely possible that cyanidin aglycone as well as peonidin aglycone were isolated because HCl was used in the extraction protocol. Although Dekazos includes the statement "the existence of the anthocyanin in free unpurified pigment extract has been confirmed in other studies" this study is not made of record in Dekazos and cannot be found by the Examiner in the prior art. Further, the statement is not clear as to whether this 'extract' was from cherries or some other form of plant matter.

Wherein Appellants argue "Examples 1 and 2 the whole cherry (including the skin) was blended in the WARING blender. Thus, cyanidin clearly occurs in nature and is in the naturally derived compositions described in the application. The hydrolyzed glycosylated anthocyanins were used to obtain enough for testing in the Examples" is not found convincing. It appears that Appellant is contending that because the extraction protocol included blending, that this would hydrolyze the cyanidin aglycone from its corresponding glycoside. There is lack of evidence in the Specification which would indicate that blending of cherries will release the glycoside from the cyanidin core structure. With regard to Appellants' statement "cyanidin clearly occurs in nature and is the naturally derived compositions described in the application" is also not convincing because, as stated above, there is no clear evidence that cyanidin occurs in nature in the aglycone form, and further no evidence that blending will provide enough shearing force in order to release the glycoside from anthocyanins to produce the aglycone form of cyanidin.

Taking Appellants' Specification as a whole, it appears that Appellants' intent is to create a composition containing 'anthocyanins, bioflavonoids and phenolics' for use as anti-inflammatory agents as per the products found in Examples 1 and 2 of the Specification, while acknowledging that cyanidin is the active constituent of anthocyanins. Specifically, page 15 of the specification indicates that "...pure anthocyanins 1-3 showed little or no activity against PGHS-1 and PGHS-2....This is probably due to the ability of anthocyanins 1 and 2 to act as oxygen carriers at high concentration and enhance the oxygen uptake. It is noted that anthocyanins are hydrolyzed in the gut of a mammal to cyanidin and other compounds and are thus effective in vivo." Subsequently, Appellants performed separate tests of cyanidin aglycone, wherein the cyanidin aglycone was specifically hydrolyzed from the corresponding glycoside structure with HCl (pages 15-17). There is nowhere in the specification as filed which indicates that cyanidin, in its aglycone structure, is purified via the protocols set forth in Examples 1 and 2 of the specification which would clearly indicate that Appellants were in possession of a mixture of anthocyanins and cyanidin. On the contrary, Appellants did not teach that cyanidin was in the mixture extracted by the protocols of Examples 1 or 2 and also did not indicate that cyanidin aglycone was purified for testing by Examples 1 or 2, but was purified by hydrolysis with HCl. Because there is no clear indication found in the Specification that the extraction protocols used in Examples 1 and 2 actually yielded cyanidin aglycone, and no clear indication in the prior art that cyanidin aglycone occurs naturally, it remains the opinion of the examiner that Appellants were not in possession of a composition comprising anthocyanin and cyanidin.

It is deemed that one skilled in the art would not determine that Appellants' protocol would yield cyanidin aglycone because HCl (or any other strong acid) was not used in the extraction protocols of Examples 1 and 2 in the specification and thus would not concur that cyanidin aglycone was present in the test of Example 6 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 29, 2006  
Patricia Leith  
Primary Examiner  
Art Unit: 1655

